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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/985,705	11/06/2001	Stan Cipkowski	3069	4302

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Edmund M. Jaskiewicz
Suite 400
1730 M Street NW
Washington, DC 20036

EXAMINER

GRUN, JAMES LESLIE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/985,705	Applicant(s) CIPKOWSKI, STAN	
	Examiner James L. Grun	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The amendment filed 14 December 2005 is acknowledged and has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16, 19, and 20 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over May et al. (WO 88/08534) in view of Sun et al. (US 5,238,652) for reasons of record.

Claims 16, 19, and 20 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over May et al. (WO 88/08534) in view of Sun et al. (US 5,238,652), and further in view of Boger et al. (US 4,518,565) for reasons of record.

Applicant's arguments filed 14 December 2005 have been fully considered but they are not deemed to be persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies, e.g. "a large flat area of the sample receiving portion...to directly contact the test sample," are not disclosed in the instant application and are not recited in the rejected claim(s). The examiner would note that certain specifics regarding test strip structure are entirely lacking in the instant specification. There is no disclosure in the instant specification regarding whether the instant test strip does or does not include an absorbent pad at the sample receiving portion. Applicant, in this regard, merely discloses that specimen is able to contact the "absorbent or sample portions" of the test strips through the sample openings (see e.g. page 12). Moreover, there is no specific teaching in the instant specification regarding whether the instant test strips do or do not include the conventional backing or sandwiching with plastic taught in May et al. Such sandwiching would

Art Unit: 1641

affect the size and shape of the “sample portion” and, as taught in some conventional test strip references (see e.g. Lee-Own et al., US 5,500,375), the “sample portion” may only be the cut end. Thus, notwithstanding applicant’s assertions to the contrary, there would seem no support for direct contact or a large flat area. Further, as set forth, May et al. specifically exemplify casings having apertures in the front or end of the casing for sample application, and specifically teach that the dry porous carrier communicates directly or indirectly with the exterior of the casing such that sample can be applied to the porous carrier (see e.g. page 3, or claims) and that combinations of features of the specifically exemplified embodiments were contemplated. For the reasons of record, one would have been motivated to provide a casing such as that depicted in Fig. 11 for a nitrocellulose test strip as depicted in Fig. 1 in view of the teachings in May et al. that such combinations were possible and that the sample receiving portion thereof was not sufficiently robust to protrude from a casing and one would have expected the combination to function as desired. The shape of the apertures and their placement on the end or front of the casing would seem obvious matters of design choice. Moreover, notwithstanding applicant’s arguments to the contrary, there is nothing found in the disclosure of May et al. that excludes bathing an entire sample receiving portion of a dry porous carrier without a porous receiving member, as depicted in Fig. 1, when contacted with a sample in a casing such as that depicted in Figs. 5 or 6 or 11.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Arguments against individual

Art Unit: 1641

aspects of the references which were not relied upon in the rejection and which do not serve to teach away from the invention as a whole, such as particular structural elements of various particular embodiments of the housings/holders of Sun et al. or of the test strips of Boger et al., were not found persuasive. For example, applicant urges that Sun et al. teach an embodiment wherein sample flows through a passage of a device housing before coming in contact with the lateral flow immunoassay test strip therein. This is not found persuasive as the reference teaches other embodiments in which an absorbent pad is found at the sample application opening of the housing and the test membrane, having the colored latex spheres sensitized or coated with detecting antibodies impregnated thereon in close proximity to the opening and the absorbent pad, is implicitly in close proximity to or in contact with the opening and absorbent pad. As set forth above, there is no disclosure in applicant's specification regarding the presence or absence of an absorbent pad at the sample receiving portion. The reference of Sun et al. is cited for its specific disclosure of membrane strips containing reagents for competitive immunoassay of drugs of abuse, i.e. the "immunoassay means" on the immunoassay test strips disclosed by applicant's specification, and not for the particularities of the housings chosen by the reference for the test strips. Applicant urges that Boger et al. do not teach lateral flow immunoassay test strips. This is not found persuasive because the reference of Boger et al. is cited for its teachings regarding means which facilitate the preferred precise parallel alignment of reagent test strips in a holder. As set forth, May et al. clearly teach apertures in casings registering with absorbent or sample receiving portions of lateral flow immunoassay test strips therein and detection of visual signal on an immunological test strip detection zone on the test strip contained in the casing. Sun et al. also teach lateral flow immunoassay test strips. The test for combining references is what

Art Unit: 1641

the combination of disclosures, taken as a whole, would suggest to one of ordinary skill in the art. See: *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); or, *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. See: *In re Bozek*, 163 USPQ 545 (CCPA 1969).

Claims 16, 19, and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-19 of copending Application No. 08/981,665 for reasons of record.

Applicant's offer to file a terminal disclaimer is noted. The rejection is maintained until it is overcome by, in particular, a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

Art Unit: 1641

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

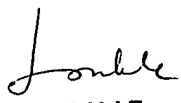
The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James L. Grun, Ph.D.
February 9, 2006



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SUPERVISORY PATENT EXAMINER
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02/11/06